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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,703	09/24/2001	Shirley Miekka	CI-0012	4291

34610 7590 07/26/2004

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EXAMINER
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JASTRZAB, KRISANNE MARIE

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/960,703

Applicant(s)

MIEKKA ET AL.

Examiner

Krisanne Jastrzab

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-90 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-90 is/are rejected.
- 7) ☒ Claim(s) 35 and 82 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Claim Objections*

Claims 35 and 82 objected to because of the following informalities: claim 35 fails to depend from a *preceding* claim, as it refers to claim 37 for dependency, claim 82 includes a typographical error in line 2 or "0about". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 29-30, 41-42, 51, 55-57 and 88-90 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Login et al., U.S. patent No. 4,994,237.

Login et al., teach a method of preserving and sterilizing biological tissues by exposing the tissue to microwave radiation. The tissues are immersed in an osmotically balanced solution (OBS) initially at room temperature and then the tissue is irradiated with microwave energy at a sufficient dose and for a sufficient time to increase the temperature of the solution to within 35°C and 50°C. After sterilization the tissue is stored in a cold sterile saline solution of OBS as soon as possible and preferably within 30 seconds of irradiation. The OBS used for storage of the tissue specimens may contain glutaraldehyde, a calcium chelating agent such as EDTA, sodium azide or

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thermisol. (See column 3, lines 53-68, and column 5, lines 5-23, and column 6, lines 3-5 and Study I).

Claims 1-7, 17-43, 45-54 and 56-89 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Platz et al., U.S. patent No. 6,187,572 B1.

Platz et al., teach a method for inactivating viral and/or bacterial contamination in blood cellular matter, such as erythrocytes and platelets, or protein fractions. The cells or protein fractions are mixed with chemical sensitizers, frozen or freeze-dried, and irradiated with, for example, UV, visible light, gamma or x-ray radiation while in a solid state. (See column 3, lines 28-66, column 8, lines 5-50, column 9, lines 35-65, column 12, lines 62-68, column 16, lines 25-68 and column 18, lines 35-45, column 19, lines 35-50, column 23, lines 33-38, and column 27, lines 50-60).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-16, 44 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al., as applied to claims 1-7, 17-43, 45-54 and 56-89 above, and further in view of Odland U.S. patent No. 5,989,498.

Odland teaches the substitution of e-beams for gamma radiation in the sterilization of biological material, particularly in cases where terminal sterilization is desired because the e-beams provide higher acceptable doses for shorter durations to achieve the same level of sterilization requiring lower dose and longer exposure periods for gamma radiation. See column 1, lines 43-60, column 2, lines 60-68, column 3, lines 5-25, column 4, lines 1-56, column 6, lines 10-20 and lines 46-68, column 7, lines 45-58 and column 10, lines 55-62).

It would have been obvious to one of ordinary skill in the art to substitute e-beams for the gamma radiation of Platz et al, because, as is taught in Odland, e-beams provide higher acceptable doses for shorter durations to achieve the same level of sterilization requiring lower dose and longer exposure periods for gamma radiation.

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With respect to claims 8-16, Odland teaches effective rates that fall within the claimed ranges for e-beam and for gamma radiation.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Wed. 6:30am-4:00pm and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Krisanne Jastrzab  
Primary Examiner  
Art Unit 1744

July 22, 2004